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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,726	01/11/2001	Gary H. Fenton	33038	8445

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EXAMINER

KIDWELL, MICHELE M

ART UNIT PAPER NUMBER

3761

DATE MAILED: 12/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,726

Applicant(s)

FENTON, GARY H.

Examiner

Michele Kidwell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

This application contains claims 1 – 10 drawn to an invention nonelected without traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 15 – 16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nowak et al. (US 4,834,731).

With respect to claim 11, Nowak et al. (hereinafter "Nowak") discloses a mounting disc for an ostomy pouch comprising a flexible plastic disc having a convex central body portion (26) and a surrounding annular rim (figure 3), a first foam disc having first and second faces (25) and having pressure-sensitive adhesive on each of said faces (col. 5, lines 15 – 24), said first foam disc having an outer diameter substantially corresponding to the outer diameter of said flexible plastic disc (figures 2 – 3), the second face of said first foam disc being adhered to the convex central body portion and the surrounding annular rim of the plastic disc (figures 2 – 3), a second

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foam disc having first and second faces and having pressure-sensitive adhesive on said first face of said second foam disc (18), said second foam disc having an outer diameter greater than the outer diameter of the flexible plastic disc (figure 7), the second face of said second foam disc being adhered to the first face of said first disc (col. 4, lines 25 – 41), an adhesive skin barrier disc having an outer diameter substantially corresponding to the outer diameter of said second foam disc (17), said skin barrier disc being adhered to the first face of the second foam disc as set forth in figure 7.

With reference to claim 15, Nowak discloses a mounting disc including a removable protective film covering another face of the skin barrier disc (35) as set forth in figure 7.

With reference to claim 16, Nowak discloses an ostomy appliance having a mounting disc adapted to the peristomal skin surfaces of an ostomate comprising a mounting disc and an ostomy pouch, said ostomy pouch comprising a flexible plastic disc having a convex central body portion (26) and a surrounding annular rim (figure 3), a first foam disc having first and second faces (25) and having pressure-sensitive adhesive on each of said faces (col. 5, lines 15 – 24), said first foam disc having an outer diameter substantially corresponding to the outer diameter of said flexible plastic disc (figures 2 – 3), the second face of said first foam disc being adhered to the convex central body portion and the surrounding annular rim of the plastic disc (figures 2 – 3), a second foam disc having first and second faces and having pressure-sensitive adhesive on said first face of said second foam disc (18), said second foam disc having an outer diameter greater than the outer diameter of the flexible plastic disc (figure 7), the

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second face of said second foam disc being adhered to the first face of said first disc (col. 4, lines 25 – 41), an adhesive skin barrier disc having an outer diameter substantially corresponding to the outer diameter of said second foam disc (17), said skin barrier disc being adhered to the first face of said second foam disc (figure 7), and said ostomy pouch comprising proximal and distal sheets of plastic film sealed at their peripheries, said proximal sheet having a stoma inlet portal therein, said inlet portal having a diameter substantially corresponding to an inside diameter of the annular rim of said flexible plastic disc, said annular rim being sealed to said proximal sheet about a zone surrounding said portal as set forth in figures 4 – 5.

With reference to claim 20, Nowak discloses a mounting disc including a removable protective film covering another face of the skin barrier disc (35) as set forth in figure 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 – 14 and 17 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nowak et al. as applied to claims 11, 15 – 16 and 20 above, and further in view of Leise, Jr. et al. (US 5,618,276).

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The difference between Nowak and claims 12 and 17 is the provision that the mounting disc include diametrically opposed and radially extending mounting loops at a periphery of the flexible plastic disc.

Leise, Jr. et al. (hereinafter "Leise") teaches a mounting disc that includes diametrically opposed and radially extending mounting loops at a periphery of the flexible plastic disc as set forth in figure 1.

It would have been obvious to one of ordinary skill in the art to modify the mounting disc of Nowak to provide diametrically opposed and radially extending mounting loops at a periphery of the flexible plastic disc because these mounting loops provide opening for receiving the connectors of a conventional support belt or strap as taught by Leise in col. 5, lines 3 – 18.

As to claims 13 – 14 and 18 – 19, absence of a critical teaching and/or unexpected result, the examiner contends that the claimed limitation is an obvious matter of design choice that does not patentably distinguish the claimed invention from the prior art.

Response to Arguments

Applicant's arguments filed October 10, 2003 have been fully considered but they are not persuasive.

In response to the applicant's argument that Nowak does not disclose a mounting disc having first and second foam discs where a second face of the second foam disc is adhered to a first face of the first disc, the examiner disagrees. The applicant is presenting arguments to support the faces of the foam discs being directly

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adhered or adjacently adhered. The claim limitations do not require the faces of the disc to be adjacent each other and the examiner contends that even if the faces are adhered to each other via other members (24,12), the second face of the second foam disc is still adhered to a first face of the first disc as required by the claim language.

In response to the applicant's argument that the foam layer is located on an ostomy appliance and the intermediate ring is located in a convex pressure ring assembly, the examiner contends that the applicant's claim language is open ended and may comprise additional elements including the appliance in which the ring is fastened to and completed by.

In response to the applicant's argument that the microporous patch has an outer diameter that is substantially larger than the outer diameter of the foam layer, the examiner disagrees. The examiner contends that the outer diameter is considered as the opening shown in figure 3, for example, which is in the middle of the ring assembly. In this instance, the diameter of the microporous patch substantially corresponds to the outer diameter of the second foam disc.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 703-305-2941. The examiner can normally be reached on Monday - Friday, 7:30am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Michele Kidwell
December 29, 2003


GLENN K. DAWSON
PRIMARY EXAMINER